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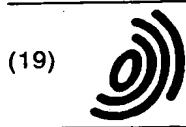
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(54) Method for assessing pulmonary stress and a breathing apparatus

(57) A method for assessing pulmonary stress, wherein a flow of respiratory gas is supplied to the lungs of a subject, an ensuing pressure is measured in relation to time and the pressure-time (P-t) relationship is analysed is disclosed. The method is characterised in that the analysis comprises the method step of determining

the profile of the pressure-time (P-t) relationship. In short, the profile is straight (2A) when no stress is present, convex (2B) when there is a risk for overdistension and concave (2C) when alveolar units are opened up. Implemented in a breathing apparatus the method can be used to assist an operator in diagnostic and therapeutic considerations in relation to a patient.

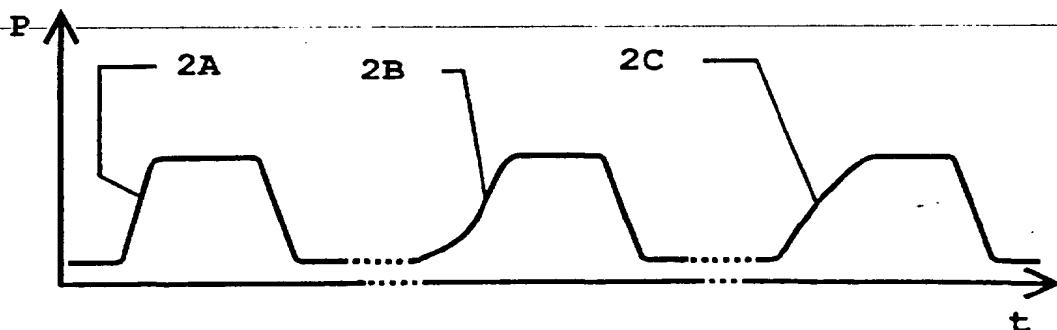


FIG. 1

Description

[0001] Method for assessing pulmonary stress and a breathing apparatus

[0002] The present invention relates to a method for determining pulmonary stress according to the preamble of claim 1.

[0003] The present invention also relates to a breathing apparatus according to the preamble of claim 5.

[0004] The present invention further also relates to a breathing apparatus according to the preamble of claim 11.

[0005] In US 4 351 344 a method and apparatus for monitoring lung compliance is disclosed. A constant flow of gas is supplied during inspiration and a pressure versus time relationship is recorded. The pressure-time relationship is analysed with respect to linearity. More specifically, the temporal length of a linear slope segment in the pressure-time relationship is determined. The temporal length can be compared with limits and an indication of the compliance status for the patient can be made based on the comparison.

[0006] The information thus obtained is, however, insufficient and inconclusive for being properly used in determinations of the status of the lung and as a tool for improving treatment of a lung.

[0007] Mechanical ventilation is used as a life saving treatment in many circumstances. But it can also aggravate pre-existing disease and even induce lung injury if the dynamics and physiology of mechanical breath delivery is not considered. The lung has an inherent tendency to collapse. During normal breathing this tendency is counteracted by the chest wall and a natural substance called surfactant.

[0008] In disease the collapsing tendency becomes more pronounced, giving rise to areas (alveolar units) collapsing early during exhalation/expiration and opening late during inhalation/-inspiration. This cyclic opening and closing of airways may initiate lung injury manifest as gross air leaks, diffuse alveolar damage, pulmonary edema and pulmonary inflammation, all of which have been termed Ventilator Induced Lung Injury (VILI). The cyclical opening and closing of alveolar units can be counteracted by the administration of a correctly set Positive End Expiratory Pressure (PEEP).

[0009] A second postulated mechanism for VILI is the delivery of large tidal volumes (which can cause volutrauma) or high end inspiratory airway pressure (which can cause barotrauma). Both may over-stretch lung tissues, leading to fluid accumulation, inflammation and increased stiffness of the lung. Baro-/volutrauma can be avoided by setting a proper tidal volume or peak pressure.

[0010] If the ventilator settings are not optimised, the period before VILI is manifest can be considered as a period of increased stress. Hence, a determination of the degree of lung stress that may follow from a specific ventilator setting can be considered as a pulmonary

stress index (PSI).

[0011] It is an object of the invention to provide a method for assessing the pulmonary stress induced by the ventilatory settings for any particular patient. In particular pulmonary stress index, PSI. PSI can be an important tool in the course of diagnosing the condition of a lung and also for determining a proper treatment causing a minimum of harm to a subject.

[0012] It is another object of the invention to provide a breathing apparatus that can perform assessments of pulmonary stress and PSI.

[0013] It is a further object of the invention to provide a breathing apparatus that can be used for obtaining a more beneficial treatment of subjects with a minimum of VILI.

[0014] A method that achieves the object is obtained in that the method according to the preamble includes the step stated in the characterising part to claim 1.

[0015] Advantageous improvements of the method are disclosed in the dependent claims to claim 1.

[0016] The method includes obtaining a pressure-time relationship based on a gas flow supplied to the lungs of a subject. By analysing the profile of the relationship, important information can be extracted. In particular by determining convexity or concavity of the profile provides relevant information.

[0017] One advantageous analysis is obtained by adopting the profile to a power equation, e.g in the form of $P_{ao} = a \cdot t^b + c$, where P_{ao} is pressure, t is time and a , b and c are constants. Determination of constant b is particularly interesting since b is a determinant of the shape of the profile. If b equals 1, the profile consists of a straight line, if b is less than 1 the profile is concave and if b is higher than 1 the profile is convex.

[0018] Convex profiles have been found to correspond to risks of progressive overdistension of lungs (decreasing compliance) and concave profiles have been found to correspond to risks associated with cyclic closing and opening of alveolar units (increasing compliance). Profiles can also be sigmoidal, i.e. include both concave and convex portions.

[0019] Analysis can be performed on pressure-time relationship on a breath-by-breath basis or on averaged values over a plurality of breaths.

[0020] Another advantageous analysis is obtained by adopting the profile to a polynomial equation, e.g in the form of $P_{ao} = \alpha + \beta \cdot t + \gamma \cdot t^2$, where P_{ao} is pressure, t is time and α , β and γ are constants. Determination of constant γ is particularly interesting since γ is a determinant of the shape of the profile. If γ equals 0, the profile consists of a straight line, if γ is less than 0 the profile is concave and if γ is higher than 0 the profile is convex.

[0021] A breathing apparatus that achieves the objects is obtained in that the apparatus according to the preamble is made according to the characterising part to claim 7.

[0022] Advantageous improvements and embodiments are evident from the dependent claims to claim 7.

[0023] Basically, the apparatus comprises a gas regulator for regulating respiratory gas flows, a pressure gauge for (directly or indirectly) measuring a pressure, preferably the airway pressure and a control unit for controlling the gas regulator to at least supply a constant flow of a respiratory gas during inspiration phases while measuring pressure in relation to time. The control unit is further adapted to perform the methods described above.

[0024] In one preferred embodiment, the control unit is adapted to compare the constant b with an interval, preferably with a lower limit between 0,5 and 0,95 and an upper limit between 1,05 and 1,5. As long as the constant b falls within the interval, there is no pulmonary stress. If the constant b falls outside the interval there is pulmonary stress. The value of the constant b thus provides both an indication of the presence of pulmonary stress and the magnitude of it. The constant b can therefore be used as a value for pulmonary stress index, PSI.

[0025] Similar results are obtained when the constant γ is used.

[0026] In another preferred embodiment, the apparatus comprises a display unit and an alarm unit. The control unit is further adapted to perform at least one out of a plurality of actions depending on e.g. the value of the constant b or γ (pulmonary stress index). It can generate an alarm when the stress index is too high or too low, indicating that a possibly injurious therapy is being delivered to a subject. It can display the stress index, as well as the P-t relationship, on the display unit. It can calculate suitable changes in control parameters for reducing pulmonary stress and display these as options for an operator on the display unit. It can automatically reset the control parameters in accordance with calculations of suitable changes in the control parameters. It can determine if recruiting manoeuvres should be provided. Hence, recommend/automatically perform recruiting manoeuvres, etc.

[0027] The apparatus according to the invention can advantageously be used for automatic re-setting of PEEP, tidal volume, airway pressure, I:E ratio or other ventilator-controlled parameters.

[0028] A breathing apparatus that achieves the objects is also obtained in that the apparatus according to the preamble is made according to the characterising part to claim 13.

[0029] Advantageous improvements and embodiments are evident from the dependent claims to claim 13.

[0030] Basically, the breathing apparatus comprises at least a first gas regulator and a second gas regulator for regulating a respiratory gas flow, at least one pressure gauge and a control unit for controlling the gas regulator based on set control parameters and for establishing a pressure-time (P-t) relationship.

[0031] To achieve a proper treatment, with a minimum of stress to the lungs, the control unit is adapted to per-

form a series of actions, corresponding to phases.

[0032] During the first phase, the control unit controls the first gas regulator and second gas regulator to provide respiration cycles having an initial tidal volume, an initial respiratory rate, an initial inspiratory time in relation to total respiration cycle time, a constant inspiratory gas flow, an initial oxygen fraction and an initial PEEP value. All the initial values can be predefined within the control unit, calculated by the control unit based on patient information, e.g. weight, diagnosis, etc., or entered via an operator interface by an operator.

[0033] During the second phase, the control unit controls the first gas regulator and second gas regulator to provide a progressive increase of the initial PEEP value and to determine the stress index. The stress index (e.g. constant b or γ) is compared with a predefined interval and when the stress index falls within the predefined interval, the control unit can proceed to the next phase.

[0034] During the third phase, the control unit controls the first gas regulator and second gas regulator to provide at least one recruiting manoeuvre having a specific inflation pressure and inflation time. The inflation pressure could be up to levels of 30 - 40 cmH₂O or even higher if necessary. The stress index is determined and compared with the predefined interval. If the stress index falls below the predefined interval, the control unit controls the apparatus to provide a further progressive increase of the PEEP value and repeat the recruiting manoeuvre(s). This is continued, until the stress index exceeds the predefined interval. Thereafter, the next phase can be commenced.

[0035] During the fourth phase, the control unit continues to determine the stress index and compare it with the predefined interval. At the same time it controls the first gas regulator and the second gas regulator to provide a progressive decrease in the PEEP value. This is continued until the stress index falls within the predefined interval.

[0036] The result of all these phases is that a non-stress setting for the apparatus is achieved. Through the operator interface, an operator can repeat the entire sequence or specific phases. It can also be beneficial if the onset of some phases requires initialisation from the operator, whereby the control unit can be adapted to display requests for proceeding on the operator interface.

[0037] In the following embodiments of the invention will be disclosed in greater detail together with the drawings.

[0038] FIG. 1 shows in a pressure-time diagram three different types of respiration profiles, and FIG. 2 shows a preferred embodiment of a breathing apparatus according to the invention.

[0039] FIG. 1 shows three different respiratory cycles in a pressure-time diagram P-t. The cycles have been obtained by measuring the pressure during constant flow inspiration, pause and expiration. The first cycle has a profile 2A during inspiration that is essentially straight, the second cycle has a profile 2B during inspi-

ration that is convex and the third cycle has a profile 2C during inspiration that is concave.

[0040] Similar curves could be obtained by determining actual lung pressure during supply of gas with a constant pressure. Determination of actual lung pressure can be made by measuring pressure within the lungs (e.g. at or near carina) or by calculating the pressure within the lungs with known methods.

[0041] The present invention is thus applicable for all situations where gas is supplied to a subject.

[0042] According to the method of the present invention, helpful information can be obtained from the profiles 2A-C. In particular, the convexity or concavity of the profile will provide essential information.

[0043] One way of analysing the profiles 2A-C is to adopt each profile to a power equation, e.g. $P_{ao}=a*t^b+c$. P_{ao} represents airway pressure or P_{tp} , but need not necessarily be measured at the airway opening. Pressure can be measured elsewhere and the airway pressure can be estimated from the measured pressure. t represents time and a , b and c are constants (for any specific profile). In particular constant b is here of interest, since it is a determinant for the shape of the profile. If $b=1$, the profile is straight, as in profile 2A, if $b>1$, the profile is convex, as in profile 2B and if $b<1$, the profile is concave, as in profile 2C.

[0044] It is of course possible to apply other mathematical algorithms for determining the profiles. One obvious alternative is to apply a polynomial function, e.g. $P_{ao}=\alpha+\beta*t+\gamma*t^2$. In this case, the constant γ is the most interesting, since it determines whether the profile is convex, concave or straight. Higher orders of polynomial functions can also be used.

[0045] Other tools are also possible to use. For instance, a straight line can be applied between the first and last co-ordinates of the P-t relationship. If the profile is convex (or essentially convex), most or all co-ordinates will lie below the straight line. If the profile is concave (or essentially concave), most or all co-ordinates will lie above the straight line. A weighting of measured data thus provides the result. Profiles having a sigmoidal shape can be stepwise analysed and provide indication on presence of both convex and concave parts (several values for b). An essentially straight profile will have its co-ordinates fairly evenly distributed on both sides of the straight line.

[0046] It may here be noted that when a constant flow of gas is supplied to the subject a pressure-volume relationship will provide the same information as the P-t relationship and may therefore be used instead. (Or, to put in another way, the pressure-volume relationship is really a pressure-time relationship since the volume V is equal to the constant flow Φ multiplied with time t ; $V=\Phi*t$.) It does not matter whether pressure is used on the y-axis or x-axis (with time or time-related variable on the other), when illustrated in a diagram.

[0047] The profiles can also be analysed by using artificial neural networks (ANN), pattern recognition sys-

tems, etc.

[0048] Returning now to the analysis described above, with b -values indicating one of the three profiles 2A-C.

5 [0049] The convex profile 2B is an indication of a decrease in compliance with increasing tidal volumes. Such decrease is correlated to progressive overdistension. This basically means that the physical limit for expansion of the ventilated alveolar units has been reached. Treatment at this level may not only cause physical injury to lung tissue, but may also have detrimental effects on blood circulation through the lungs.

10 [0050] The concave profile 2C is an indication of an increase in compliance with increasing tidal volumes. Such increase is correlated to the opening up of alveolar units within the lungs. If a treatment were to display this kind of profile breath after breath (or as an average over a plurality of breaths), it is a sign of cyclic closing and opening of alveolar units. Such treatment is not ideal and may be injurious to the lungs.

15 [0051] In other words is it beneficial to the patient to arrive at a treatment where the straight profile 2A predominates. This means situations where constant $b=1$.

20 [0052] Based on this, the constant b can be used an indication of the pulmonary stress. With b as a pulmonary stress index (PSI), the value of the stress index can be used to inform an operator of pulmonary stress. Since there are always variations in the real world, a normal or minimal stress index can be allowed to vary within a predefined interval. The interval could e.g. be 0,9 - 1,1. The interval can be set by an operator before starting a treatment.

25 [0053] Referring now to FIG. 2 which shows a breathing apparatus according to the invention. The breathing apparatus is generally indicated with numeral 4. The apparatus 4 can be connected to a subject, or patient 6. Essentially any animal with lung-dependent respiration can be contemplated as patient.

30 [0054] Gases can enter the apparatus 4 via a first gas inlet 8A and a second gas inlet 8B. The gases are then mixed into a selected respiratory gas in a first gas regulator 10. One gas inlet would be sufficient if the respiratory gas was mixed outside the apparatus 4. More gas inlets can be used where the respiratory gas is to consist of more than two gases. In this embodiment air and oxygen are used as gases.

35 [0055] The gas regulator 10 also regulates pressure and flow of the respiratory gas. The gas regulator 10 normally includes one or more valves for regulating down high-pressure gases, but in portable breathing apparatuses the regulator could also consist of a fan, compressor or similar device for generating a gas flow.

40 [0056] After the gas regulator 10, the respiratory gas passes a first pressure gauge 12 and a first flow meter 14. It then passes through an inspiration line 16 to a patient line 18 and into the patient 6.

45 [0057] From the patient 6 the respiratory gas will flow back through the patient line 18, into an expiration line

20 and via a second flow meter 22, a second pressure gauge 24 and a second gas regulator 26 to a respiratory gas outlet 28. The second gas regulator 26 is normally used to control respiratory gas flow during expiration for upholding a set end pressure (Positive End Expiratory Pressure - PEEP).

[0058] The pressure gauges 12, 24 and flow meters 14, 22 need not be located as shown. They can, for instance, be built in within the gas regulators 10, 26. They can also be located elsewhere in the gas flow paths of the apparatus (such as inspiration line 16 and/or patient line 18 and/or expiration line 20). In particular is it possible to locate a pressure gauge within the patient 6 to measure lung or airway pressure. However, based on measurements from pressure gauges 12, 24 and flow meters 14, 22 as shown, corresponding values of e.g. airway pressure can be calculated in known manner.

[0059] The operation of the first gas regulator 10 and the second gas regulator 26 is controlled by a control unit 30. The control unit 30 also receives information from the pressure gauges 12, 24 and flow meters 14, 22. Based on the measured information the control unit 30 can, inter alia, determine the above disclosed stress index. The control unit 30 can comprise of any combination of known control components. It could for instance be micro processor based system including one or several processors and memories. Software programming could be used for carrying out the functions. It could also comprise, or include, hardwire components such as EPROM or similar. Other functions and tasks that the control unit 30 can perform are discussed below.

[0060] Via an operator interface 32 an operator of the apparatus 4 can communicate with, mainly, the control unit 30 via a first communication link 34. A display 36 can show programmed parameters, selectable functions and parameters as well as diagrams, suggested parameter, parameter waves, stress index and any conceivable information. The display 36 can consist of a CRT-screen, flat screen with or without touch sensitivity, plasma screen or any suitable screen for displaying images. The display 36 need not be integrated with the operator interface 32 and several displays can be used for one apparatus 4.

[0061] Additional equipment (e.g. further displays, PC, Intranet link to databases or remote monitoring stations, Internet link, etc.) is generally indicated with designation numeral 38 and can be connected to the apparatus 4 for communication. It can be connected to the control unit 30 via a second communication link 40 and/or to the operator interface 32 via a third communication link 42.

[0062] One example of how the apparatus 4 can be used for a patient 6 will now be described.

[0063] Suppose that a patient 6 having partially or completely collapsed lungs is connected to the apparatus 4. Although keeping the patient 6 alive is the primary goal, it should be done with minimum risk of causing further damage to the lungs. The control unit 30 is therefore

programmed/constructed to perform a number of actions. These actions can be divided into phases, which can be carried out automatically or after initiative of an operator.

5 [0064] The first phase consist essentially of life maintaining measures. The control unit 30 controls the first gas regulator 10 and second gas regulator 26 to provide respiration cycles having an initial tidal volume, an initial respiratory rate, an initial inspiratory time in relation the respiration cycle time, an initial oxygen fraction (FiO₂) and an initial PEEP value.

[0065] The initial values can be pre-programmed into the control unit 30, but are preferably either entered by the operator via the operator interface 32 or calculated by the control unit 30 based on patient data such as age, weight, diagnosis, or other available information regarding the status of the patient. FiO₂ could e.g. initially be set to 100%.

[0066] During the respiration cycles the control unit 30 also determines the stress index on a regular basis and compares the stress index with the predefined interval mentioned above. The interval can have a lower limit of ca. 0,6 - 0,95 and an upper limit of ca. 1,05 - 1,4, or any other interval reasonable in view of the patient's 20 initial condition. In the current example with a patient 6 with collapsed lungs, the stress index will most likely fall below the predefined interval.

[0067] The second phase is basically meant to start to open up the lungs. The control unit 30 will then proceed by (mainly) controlling the second gas regulator 26 to achieve a progressive increase in PEEP. The increase will continue until the stress index exceeds the lower limit, i.e. falls within the predefined interval. The increments by which PEEP is increased can be pre-programmed, calculated by the control unit 30 or entered by the operator.

[0068] In the third phase proper opening up of the lungs is the aim. To do this one or more recruiting manoeuvres are performed by the apparatus 4. A recruiting manoeuvre essentially consists of a prolonged inspiration (or rather inflation) at an elevated pressure in relation to the initial settings. The inspiration can last up to about a minute and the pressure can be up to 40 - 60 cmH₂O. Again, the values can be higher or lower depending on the specific circumstances at hand. Control parameters for the recruiting manoeuvre can be pre-programmed, calculated by the control unit 30 or entered by the operator. Other recruiting manoeuvres can also be used.

[0069] After the recruiting manoeuvre(s) stress index is again determined and compared with the predefined interval. Should the stress index be lower or even within the interval (but not optimal), the control unit 30 will control the second gas regulator 26 to increase PEEP again.

[0070] Another recruiting manoeuvre or manoeuvres is then supplied, followed by new determination of stress index.

[0071] This procedure of recruiting manoeuvre(s) and increase of PEEP value continues until stress index exceeds the upper limit of the predefined interval. This means that the lung has been fully recruited and can be regarded as fully open.

[0072] The fourth phase aims at reaching a proper setting for PEEP. The control unit 30 therefore controls the apparatus 4 to decrease PEEP, while determining stress index. When stress index falls within the interval, the settings regarding PEEP are essentially optimised.

[0073] Since the lungs are open, FiO_2 can be lowered. A proper decrease of FiO_2 is made when saturation of oxygen is decreased by 1-2%. A meter for saturation and, if required, other patient data is indicated with reference numeral 44 in FIG. 2. The decrease can be performed by the operator or by the control unit 30 (requiring access to saturation measurements).

[0074] When the operator wishes to select another respiration mode, the control unit 30 can display the determined no stress setting on the display 36 as a suggestion to the operator.

[0075] Similar procedure can of course be performed when the profile of the P-t relationship is analysed in other ways (as described in connection with the method according to the invention). The profile will inevitably display convexity when there is a risk for overdistension and concavity when alveolar units are being opened.

[0076] Although not explicitly mentioned above, the breathing apparatus can of course be constructed or adapted to perform or carry out any function known to persons skilled in the art.

Claims

1. Method for assessing pulmonary stress, wherein a flow of respiratory gas is supplied to the lungs of a subject, an ensuing pressure is measured in relation to time and the pressure-time (P-t) relationship is analysed, **characterised** in that the analysis comprises the method step of determining the profile of the pressure-time (P-t) relationship.
2. Method according to claim 1, **characterised** in that the determination of the profile comprises determination of convexity/concavity of the profile.
3. Method according to claim 1 or 2, **characterised** in that the determination of the profile comprises the step of adopting the pressure-time (P-t) relationship to the power equation $P_{ao}=a*t^b+c$, and at least determining the constant b as a determinant for the profile, whereby the profile is concave if $b<1$, corresponding to an increase in compliance, the profile is straight if $b=1$, corresponding to a constant compliance and the profile is convex if $b>1$, corresponding to a reduction in compliance.
4. Method according to claim 1 or 2, **characterised** in that the determination of the profile comprises the step of adopting the pressure-time (P-t) relationship to the polynominal equation $P_{ao}=\alpha+\beta*t+\gamma*t^2$, and at least determining the constant γ as a determinant for the profile, whereby the profile is concave if $\gamma<0$, corresponding to an increase in compliance, the profile is straight if $\gamma=0$, corresponding to a constant compliance and the profile is convex if $\gamma>0$, corresponding to a reduction in compliance.
5. Method according to any of the preceding claims, **characterised** in that the determination of the profile is made on a breath-by-breath basis.
6. Method according to any of the claims 1 to 4, **characterised** in that the determination of the profile is made on an average over a plurality of breaths.
7. Breathing apparatus comprising at least one gas regulator for regulating a respiratory gas flow, at least one pressure gauge and a control unit for controlling the gas regulator based on set control parameters and for establishing a pressure-time (P-t) relationship, **characterised** in that the control unit is adapted to perform the method according to any of the claims 1-6.
8. Breathing apparatus according to claim 7, wherein the control unit is adapted to perform the method according to any of claims 3 and 4 or any of claims 5 and 6 in combination with any of claims 3 and 4, **characterised** in that the control unit is further adapted to compare the determined constant (b or γ) with a predefined interval and establish that if the determined constant (b or γ) is within the predefined interval a minimum of pulmonary stress of a subjects lungs is present, if the determined constant (b or γ) is below the predefined interval pulmonary stress due to alveolar opening and closing is present and if the determined constant (b or γ) is above the predefined interval alveolar overdistension is present.
9. Breathing apparatus according to claim 8, **characterised** in that the predefined interval for the determined constant b consists of a lower limit between 0,5 and 0,95 and an upper limit between 1,05 and 1,5.
10. Breathing apparatus according to any of the claims 7 to 9, **characterised** in that the apparatus further comprises a display unit for displaying information to an operator pertaining to the operation of the apparatus and an alarm unit and in that the control means is adapted to perform at least one of the following actions based on the determination of the profile of the pressure-time (P-t) relationship: gen-

erating an alarm on the alarm unit; generating a warning on the display unit that pulmonary stress is present; determining a change in at least one control parameter; displaying the determined change on the display unit; automatically re-setting the control parameters according to the determined change; displaying a recommendation for recruiting manoeuvres on the display unit; and automatically performing recruiting manoeuvres.

11. Breathing apparatus according to claim 8, **characterised** in that the control parameter relates to one of the following: Positive End Expiratory Pressure (PEEP), fraction of oxygen in the respiratory gas (FiO_2) and tidal volume (V_T).

12. Breathing apparatus according to claim 10 or 11, **characterised** in that the control unit is adapted to determine the change in control parameter based on the determined profile of the pressure-time (P-t) relationship.

13. Breathing apparatus comprising at least a first gas regulator and a second gas regulator for regulating a respiratory gas flow, at least one pressure gauge and a control unit for controlling the gas regulator based on set control parameters and for establishing a pressure-time (P-t) relationship, **characterised** in that the control unit is adapted to perform the following actions: during a first phase control the first gas regulator and second gas regulator to provide respiration cycles having an initial tidal volume, an initial respiratory rate, an initial inspiratory time in relation to total respiration cycle time, a constant inspiratory gas flow, an initial oxygen fraction and an initial PEEP value; during a second phase control the first gas regulator and second gas regulator to provide a progressive increase of the initial PEEP value, perform the method according to, compare the constant (b or γ) with a predefined interval and when the constant (b or γ) falls within the predefined interval proceed to the next phase; during a third phase control the first gas regulator and second gas regulator to provide at least one recruiting maneuver having a specific inflation pressure and inflation time, determine the constant (b or γ), compare the constant (b or γ) with the predefined interval and if the constant (b or γ) falls below the predefined interval provide a further progressive increase of the PEEP value and repeat the at least one recruiting maneuver until the constant (b or γ) falls above the predefined interval, whereupon the next phase can be commenced; during a fourth phase determine the constant (b or γ), compare the constant (b or γ) with the predefined interval and control the first gas regulator and second gas regulator to provide a progressive decrease in the PEEP value, until the constant (b or γ) falls within the predefined interval.

14. Breathing apparatus according to claim 13, **characterised** in that the apparatus comprises an operator interface the initial tidal volume, initial respiratory rate, initial inspiratory time in relation to total respiration cycle time, initial oxygen fraction and initial PEEP value can be entered to the control unit via an operator interface.

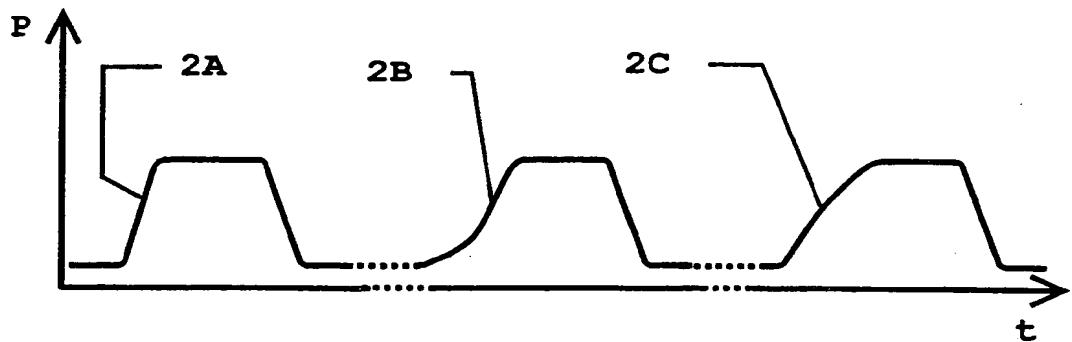


FIG. 1

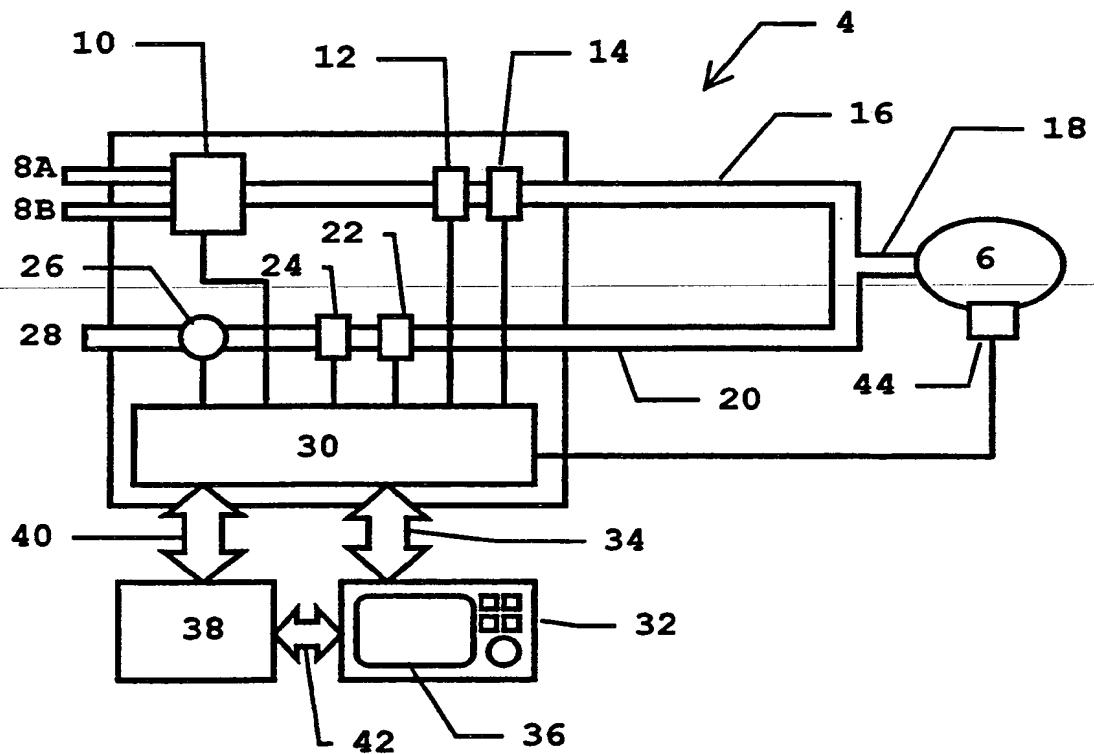


FIG. 2

(19)



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(57) A method for assessing pulmonary stress, wherein a flow of respiratory gas is supplied to the lungs of a subject, an ensuing pressure is measured in relation to time and the pressure-time (P-t) relationship is analysed is disclosed. The method is characterised in that the analysis comprises the method step of determining

the profile of the pressure-time (P-t) relationship. In short, the profile is straight (2A) when no stress is present, convex (2B) when there is a risk for overdistension and concave (2C) when alveolar units are opened up. Implemented in a breathing apparatus the method can be used to assist an operator in diagnostic and therapeutic considerations in relation to a patient.

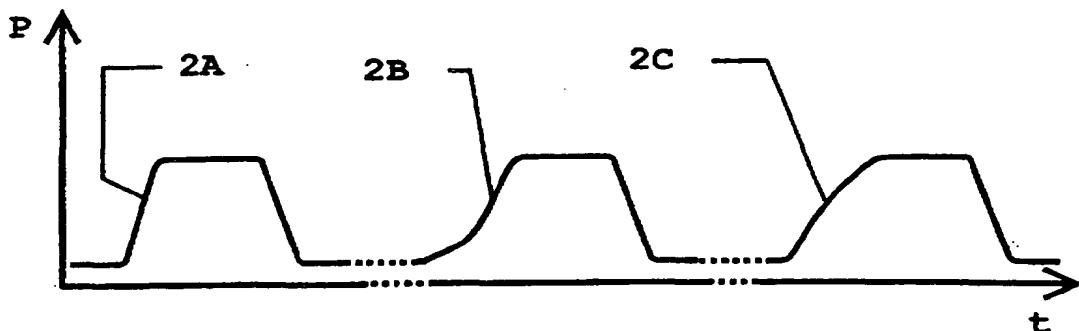


FIG. 1



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which under Rule 45 of the European Patent Convention EP 00 71 0030
shall be considered, for the purposes of subsequent
proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.7) A61B5/085 A61M16/00 TECHNICAL FIELDS SEARCHED (Int.Cl.7) A61M A61B
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
D, X	US 4 351 344 A (STENZLER ALEX) 28 September 1982 (1982-09-28) * column 3, line 48 - column 7, line 7; figures 1,2,6 *	7, 10	
A	---	11-14	
X	US 4 393 869 A (BOYARSKY ABRAHAM ET AL) 19 July 1983 (1983-07-19) * column 2, line 55 - column 3, line 51 * * column 7, line 54 - column 10, line 17; figures 2,4,6,8 *	7	
A	---	10-12	
X	EP 0 776 672 A (SIEMENS ELEMA AB) 4 June 1997 (1997-06-04) * column 1, line 51 - column 4, line 50; figures 1,2 *	7	
A	---	10-13	
A	EP 0 671 180 A (SIEMENS ELEMA AB) 13 September 1995 (1995-09-13) * column 6, line 24 - column 10, line 42; figures 1,4 *	7-13	
	---	-/-	
INCOMPLETE SEARCH			
The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.			
Claims searched completely:			
Claims searched incompletely:			
Claims not searched:			
1-6			
Reason for the limitation of the search:			
Article 52 (4) EPC - Diagnostic method practised on the human or animal body			
Place of search	Date of completion of the search	Examiner	
MUNICH	16 October 2002	Artikis, T	
CATEGORY OF CITED DOCUMENTS			
X: particularly relevant if taken alone		T: theory or principle underlying the invention	
Y: particularly relevant if combined with another document of the same category		E: earlier patent document, but published on, or after the filing date	
A: technological background		D: document cited in the application	
O: non-written disclosure		L: document cited for other reasons	
P: intermediate document		&: member of the same patent family, corresponding document	



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CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

- Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):

- No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

- All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

- As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

- Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

- None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:



European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number

EP 00 71 0030

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
A	<p>WO 87 00928 A (EME ELECTRO MEDICAL EQUIP) 12 February 1987 (1987-02-12)</p> <p>* page 3, line 13 - line 34 *</p> <p>* page 8, line 23 - page 9, line 23; figure 2 *</p> <p>-----</p>	7,10	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 7-12

Breathing apparatus comprising at least one gas regulator, at least one pressure gauge and a control unit for controlling the gas regulator based on set control parameters and for establishing a pressure-time relationship.

2. Claims: 13-14

Breathing apparatus comprising at least two gas regulators, at least one pressure gauge and a control unit for controlling the gas regulator based on set control parameters, for establishing a pressure-time relationship and for performing four phase controls.

ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.

EP 00 71 0030

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

16-10-2002

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 4351344	A	28-09-1982	CA EP IT JP WO	1175910 A1 0065539 A1 1145731 B 57501717 T 8201654 A1	09-10-1984 01-12-1982 05-11-1986 24-09-1982 27-05-1982
US 4393869	A	19-07-1983	CA	1180393 A1	01-01-1985
EP 0776672	A	04-06-1997	SE EP JP SE US	504285 C2 0776672 A1 9173456 A 9504312 A 5915381 A	23-12-1996 04-06-1997 08-07-1997 23-12-1996 29-06-1999
EP 0671180	A	13-09-1995	SE DE EP JP SE US	501560 C 69430189 D1 0671180 A1 7265427 A 9400487 A 5575283 A	13-03-1995 25-04-2002 13-09-1995 17-10-1995 13-03-1995 19-11-1996
WO 8700928	A	12-02-1987	WO	8700928 A2	12-02-1987